

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF NEW YORK

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IN RE BAUSCH & LOMB, INC.)  
SECURITIES LITIGATION )

) MASTER FILE NO.: 06-CV-6294  
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**INTRODUCTION**

Plaintiffs bring this class-action lawsuit against Bausch & Lomb Incorporated ("B&L"), and various individual<sup>1</sup> and corporate defendants,<sup>2</sup> (collectively "defendants") pursuant to sections 10(b) of the Securities Exchange Act of 1934, as amended, 15 U.S.C. §§ 78j(b), Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5 and section 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. § 78t(a).<sup>3</sup> Plaintiffs allege B&L overstated its net income from 2003 through 2005 due to accounting fraud perpetrated by B&L subsidiaries which affected B&L's consolidated financial statements. As a result of these overstatements, plaintiffs allege that B&L's quarterly and annual reports during the class period, January 29, 2004 through May 3, 2006 (the "Class Period"), and its quarterly press releases announcing quarterly annual results were materially false and misleading. Plaintiffs claim that

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<sup>1</sup>The individual defendants include: Ronald L. Zarrella ("Zarrella"), Stephen C. McCluski ("McCluski"), John M. Loughlin ("Loughlin"), Dwain L. Hahs ("Hahs"), Angela J. Panzarella ("Panzarella"), Robert B. Stiles ("Stiles") and Geoffrey F. Ide ("Ide"). The Amended Complaint filed on January 7, 2008 also includes a former employee of the Indian subsidiary, B&L Eyecare (India) Pvt. Ltd. ("BL India"), J.P. Singh ("Singh") (collectively "Individual Defendants").

<sup>2</sup>The Amended Complaint added for the first time as defendants, B&L's subsidiaries including, B&L Industria Otica, Ltda. in Brazil ("BLIO"), B&L Korea Ltd. ("BL Korea"), BL India and B.L.J. Company Ltd. ("BL Japan") as well as its joint venture in China, B&L China Inc. ("BL China").

<sup>3</sup>Defendants claim that Count I purports to allege violations of Section 10(b) of the Exchange Act and Rule 10b-5 by all defendants, and Count II purports to allege a claim for "control person" liability under Section 20(a) of the Exchange Act. Defendants further contend that although Count II is captioned "against all defendants," its allegations pertain only to the individual defendants and assert that they are controlling persons of B&L.

when B&L finally disclosed its subsidiaries' fraud and B&L's grossly deficient internal controls, the price of B&L stock dropped and plaintiffs suffered economic losses. Plaintiffs also claim accounting fraud with respect to B&L's product, ReNu with MoistureLoc ("MoistureLoc"). In addition, plaintiffs allege that B&L made false and misleading statements regarding the economic status and business prospects of B&L as it related to MoistureLoc in an effort to artificially inflate the price of B&L stock. Plaintiffs claim that they purchased B&L stock at inflated prices, and suffered economic losses when the stock rapidly lost value in 2006 when the truth about MoistureLoc became known to the market.

By motion dated March 7, 2008, defendants move to dismiss plaintiffs' Amended Complaint pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure, and the Private Securities Litigation Reform Act of 1995 ("PSLRA"). Defendants claim that the plaintiffs' Amended Complaint fails to state a claim upon which relief may be granted. Moreover, defendants contend that the claims against BLIO should be dismissed as time barred under the relevant statute of limitations. Further, defendants claim that the allegations against defendant Singh should be dismissed because the Court lacks personal jurisdiction over him.<sup>4</sup> For the reasons set forth below, I hereby grant

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<sup>4</sup>Defendants assert that none of the foreign defendants named in the Amended Complaint, including all of the B&L subsidiaries and Singh, have been served with process. Defendants asserts that all defenses under Fed. R. Civ. P. 12(b)(4) and (5) are reserved as to these defendants. However, in the interest of judicial economy, the challenges to the sufficiency of the Amended Complaint outlined in defendants' brief are asserted on behalf of all defendants.

defendants' motion to dismiss, and dismiss plaintiffs' Complaint with prejudice.

### **BACKGROUND**

Unless otherwise noted, the following facts are taken from plaintiffs' First Consolidated Amended Complaint For Violations of the Federal Securities Laws ("Complaint"), including documents incorporated by reference or upon which plaintiffs relied in drafting the Complaint, as well as from public documents which B&L filed with the Securities and Exchange Commission ("SEC").<sup>5</sup>

#### **I. The Parties**

Plaintiffs claim that they bought B&L stocks and bonds and are suing on behalf of a putative class of investors who purchased publicly traded B&L securities between January 29, 2004 and May 3, 2006 (the "Class Period").<sup>6</sup> B&L is a corporation that develops, manufactures and markets eye health products and whose headquarters are located in Rochester, New York. The products by B&L are sold in over 100 countries, including through numerous wholly or partly owned subsidiaries.

At all relevant times, defendant Zarrella was B&L's Chief Executive Officer ("CEO") and defendant McCluski was its Chief Financial Officer ("CFO"). Defendant Loughlin was Senior Vice President

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<sup>5</sup>See Chambers v. Time Warner, Inc., 282 F3d 147, 152 (2d Cir.2002).

<sup>6</sup>Lead Plaintiff Structural Ironworkers Local Union #1 Annuity, Pension and Welfare Funds ("Structural Ironworkers") bought B&L publicly traded securities during the relevant time period. Lead Plaintiff Police and Fire Retirement System of the City of Detroit ("Detroit P&F") also purchased B&L publicly traded securities during the relevant time period.

and President of B&L's Asia Division until May 2006 when he became a Senior Vice President of B&L. Defendant Hahs was B&L's Senior Vice president - Global Operations and Engineering from 2000 through May 2006. In addition, defendant Panzarella was B&L's Corporate Vice President, Global Vision Care and Robert B. Stiles was Senior Vice President and General Counsel of B&L. Further, defendant Ide was B&L's Vice President and President of Japan Operations from 1999 to 2005 and defendant Singh was the Managing Director of BL India. Defendant, BLIO is B&L's Brazilian subsidiary. While B&L owns 80% of BL Korea and BL India is owned by B&L through its subsidiary Bausch & Lomb South Asia Holding Company. In addition, BL Japan is B&L's wholly-owned Japanese subsidiary and BL China is B&L's joint venture in China.

## **II. Accounting Irregularities Leading to B&L's Restatement of Financial Earnings**

### **A. B&L's Subsidiaries**

#### **1. BLIO**

On October 25, 2005, B&L announced that in September, its Audit Committee began an independent investigation into alleged misconduct by local managers at BLIO, which had been reported to B&L's senior management by a BLIO employee.<sup>7</sup> The investigation revealed that BLIO's general manager, controller and other employees had mischaracterized \$600,000 in expenses to fund an unauthorized pension arrangement for themselves; avoided payroll tax obligations; and misused corporate

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<sup>7</sup>B&L maintained employee hotlines and encouraged its personnel to report any violation of the company's Code of Conduct. Pursuant to those B&L hotlines, in the Fall of 2005, employees reported possible accounting problems in Brazil and Korea.

assets for personal benefit. In addition, the investigation found that Brazilian tax authorities made assessments of \$33 million in unpaid taxes, penalties and interest in prior periods that BLIO's local managers failed to report to B&L and thus were not properly reserved on BLIO's books.

Plaintiffs claim that BLIO's failure to reserve for tax assessments and penalties was related to BLIO's illegal practice of purchasing tax credits in Brazil from other entities. According to CW1 (BLIO's former general manager), beginning in 2000, BLIO purchased tax credits associated with soy bean exports from a broker even though BLIO had nothing to do with soy bean exports. This practice was allegedly known to B&L headquarters in Rochester where lawyers modified BLIO's legal operating documents to include the business of soy beans. B&L's managers in its regional and headquarters offices endorsed the practice of using "soy bean" related tax credits as a means of improving BLIO's profitability and increasing B&L's rate of return on its Brazilian operations.

The \$33 million tax assessment, which was later reduced by Brazilian tax authorities to approximately \$11 million, was small compared to B&L's net sales for 2004, as restated, of more than \$2,223 million; and BLIO's sales accounted for just 0.9% of that amount. Further, B&L voluntarily reported the BLIO matter to the Securities and Exchange Commission ("SEC")<sup>8</sup> and terminated the BLIO general manager and

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<sup>8</sup>On June 13, 2008 counsel for defendants submitted a letter to the Court indicating that the SEC advised B&L that it has determined to close its investigation of B&L without taking any enforcement action. A copy of the SEC letter was attached. By letter dated June 17, 2008, plaintiffs responded stating that the SEC staff's inaction is

controller responsible for the misconduct. See Affidavit of Won S. Shin ("Shin Aff.") Ex. 7. B&L disclosed that it would consider, in consultation with its independent auditor, whether the Generally Accepted Accounting Principles ("GAAP") required any restatement of prior-period financial results and whether there were material weaknesses in B&L's internal controls.

B&L issued a press release on December 22, 2005 stating that the Audit Committee investigation had not found any evidence that anyone outside BLIO knew or was involved in the misconduct in Brazil, and that it had discovered evidence showing that BLIO's former general manager and controller caused misleading records to be created in order to prevent B&L's senior management from detecting their misconduct. See Shin Aff. Ex. 8. The Board of Directors concluded that the company should restate its financial results for fiscal year 2000 through the second quarter of 2005. On February 7, 2007, B&L filed its Form 10-K for 2005. The 10-K presented restated financial data for 2001 through 2005 and reported the final results of the accounting investigation and review. According to the Complaint, during the Class Period, B&L overstated its 2003 net income by 18%, 2004 net income by 4%, first quarter 2005 net income by 4% and second quarter 2005 net income by 20%.

## 2. BL Korea

As discussed above, pursuant to B&L's employee hotline, in the Fall of 2005 employees reported possible accounting problems at BL

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not evidence of an absence of wrongdoing by defendants.

Korea. As a result, B&L's December 22, 2005 press release also revealed that the Audit Committee started investigating revenue recognition practices at BL Korea. Similar to BLIO, BL Korea represented only a small portion of B&L's consolidated business, generating approximately \$33 million, which is \$1.5% of B&L's 2004 net sales of \$2,233 million. In accordance with B&L's existing compliance program, on October 26, 2005 Zarrella sent a communication to all B&L employees urging them to continue to use all available channels to report any possible violations of B&L policies. Accordingly, in November 2005 employees at BL Korea reported certain concerns. B&L made a disclosure that it had voluntarily reported the BL Korea matter to the SEC and would consider whether GAAP required additional adjustments to prior-period financial statements.

By March 17, 2006, B&L reported that, due to the BLIO and BL Korea investigations, it had undertaken an expanded review of revenue recognition practices at other foreign subsidiaries. See Shin Aff. Ex. 9. Moreover, B&L revealed that the review included issues related to transactions with distributors in Japan and India, which might result in additional adjustments to the restated financials. See id. B&L further reported on May 11, 2006 that it had started examining sales-related reserves in China. See id. Ex. 10. In the following months, B&L filed reports with the SEC disclosing the evolving scope of its ongoing accounting review. See id. Exs. 11-12.

#### **B. B&L's Internal Controls**

Plaintiff claims that in its 2003 and 2004 10-K forms, B&L and defendants Zarrella and McCluski stated that "the Company's Chairman

and [CEO] and the Company's Senior Vice President and [CFO] have concluded that as of the end of the period covered by this report, the Company's disclosure controls and procedures were effective in timely alerting them to material information relating to the Company (including its consolidated subsidiaries) required to be included in the Company's periodic filings with the [SEC]." Moreover, in the 2003 and 2004 10-K forms, Zarrella and McCluski certified that they were responsible for establishing and maintaining disclosure controls and procedures and that they had done the following:

Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;

Disclosed to its auditors and audit committee "[a]ll significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information" and "[a]ny fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting."

However, plaintiffs allege that defendants B&L, Zarrella, and McCluski admitted in the 2005 10-K form, which was filed on February 7, 2007 that B&L assurances were false and the internal controls were



incapable of detecting the frauds at numerous subsidiaries.<sup>9</sup> In addition, plaintiffs contend that B&L, Zarrella and McCluski summed up these deficiencies by commenting that "as of December 31, 2005, the Company's internal control over financial reporting was not effective based on the criteria in *Internal Control-Integrated Framework* issued by the COSO" and admitted that these deficiencies "could result in a material misstatement to the Company's interim or annual consolidated financial statements and disclosures which would not be prevented or detected." Of significance to the subsidiaries' fraud are the following alleged admissions by B&L, Zarrella and McCluski:

"[T]he Company did not adequately and consistently reinforce the importance of adherence to controls and the Company's code of conduct, which contributed to certain of the restatement items that occurred across a broad range of the Company's operational and functional area."

"[T]he Company did not establish and maintain effective corporate and regional management oversight and monitoring of operations to detect subsidiaries' managements' override of established financial controls and accounting policies, execution of improper transaction and accounting entries to impact revenue and earnings, and reporting of these transactions to the appropriate finance personnel[.]"

"[T]he Company did not maintain effective controls to provide reasonable assurance that customer arrangements were adequately reviewed by the appropriate persons at such subsidiaries to

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<sup>9</sup>According to the Complaint, B&L's alleged internal control deficiencies included the following: failure to establish and maintain effective and regional management oversight; failure to monitor the actions of its subsidiaries' managements; failure to employ sufficient personnel with an appropriate level of knowledge, experience and training in internal audit; failure to employ sufficient personnel with an appropriate level of knowledge, experience and training in the application of internal controls over financial reporting, failure to employ sufficient personnel with an appropriate level of knowledge, experience and training in the application of income tax accounting, failure by senior management to maintain an ethical environment, failure to review and approve new employee benefit plans, failure to adequately review customer sale arrangements, an ineffective program to prevent and detect employee fraud, an ineffective quarterly financial reporting and close process, and ineffective controls over accounting reserves; subsidiary/distributor controls; revenue recognition; accounting receivable; distributor inventory; sales orders, returns and exchanges; credit terms and product discounting; and equipment installation.

identify and provide reasonable assurance regarding the proper application of the appropriate method of revenue recognition in accordance with GAAP."

The Complaint includes allegations relating to two individuals whom plaintiffs identify as confidential witnesses. Confidential Witness #1 (CW1), the former general manager of BLIO, was one of the people who was fired by B&L for BLIO's accounting improprieties. CW1 states that B&L's actual oversight over BLIO was deficient and that B&L's internal auditors in Rochester had not visited BLIO since 2001, conducted internal controls merely by sending questionnaires to local managers, and that it was only after problems at BLIO began to surface publicly that the Rochester auditors spent any time examining BLIO. CW1 alleges that had the internal auditors adequately examined BLIO's financial records, they would have discovered the misappropriations since it was recorded over a multi-year period.

B&L claims that each year from 2000 through 2004, B&L's independent auditor, Pricewaterhouse-Coopers ("PwC"), conducted an audit of the Company's books and records, including audits of subsidiary records, and opined that B&L's financial statements "present[ed] fairly, in all material respects, the financial position of B&L and its subsidiaries "in conformity with [GAAP]." See Shin Aff. Exs. 1-5. After the Sarbanes-Oxley Act's internal control regulations came into force, B&L's management conducted an evaluation of the company's internal control over financial reporting and concluded that at year-end 2004 these controls were effective. Based on an evaluation of management's assessment and its own audit, PwC opined that

management's assessment was fair and that B&L's internal controls were effective.<sup>10</sup>

### **C. Disclosures Regarding BLIO**

B&L filed a form 8-K on October 26, 2005 disclosing that it might delay the filing of its 10-Q for the third quarter pending the results of an investigation into allegations of improper conduct by BLIO management. In addition, the 8-K revealed that BLIO management had "engaged in improper management and accounting practices, including, among other things, the mischaracterization of approximately \$600,000 in expenses to fund an approximately \$1.5 million, unauthorized local pension arrangement for the benefit of themselves and other members of local management, the avoidance of Brazilian payroll tax obligations, the amount of which has not yet been determined, and the misuse of Company assets for personal benefit." Moreover, "Brazilian tax authorities have made tax assessments relating to or arising from Brazilian VAT, social contribution, income and certain import-related taxes against BLIO for unpaid taxes totaling approximately \$5 million, interest of approximately \$7 million, plus approximately \$21 million in claimed penalties which relate back to various earlier periods."

Further, B&L revealed that it was considering whether any restatement of prior-period financial statements would be required and would assess its internal control over financial reporting, "including,

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<sup>10</sup>"[I]n our opinion, management's assessment ... that the Company maintained effective internal control over financial reporting as of December 25, 2004 ... is fairly stated, in all material respects .... Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 25, 2004 ...." See Shin Aff. Ex 5

in particular, its control over foreign tax matters, and whether there has been any material weakness in the Company's internal controls." In response to these announcements, the price of B&L stock dropped \$2 per share. On December 22, 2005, B&L filed Form 8-K that disclosed the following:

B&L expected to restate its financial results for the fiscal years 2000 through 2004 and the first and second quarters of 2005 due to the BLIO matters.

B&L had "preliminarily identified a material weakness relating to detection and prevention of management fraud causing the override of existing controls, particularly in the area of tax reporting in the Company's Brazilian subsidiary.

B&L's assurances for the 2004 fiscal year that its internal controls were effective "should no longer be relied upon."

The Audit Committee was investigating revenue recognition practices in BL Korea.

Plaintiffs claim that as a result of these disclosures, the price of B&L stock dropped by 15%. According to the Complaint, most of that price decline occurred on December 23, which was the first trading day following the disclosures, from \$79.07 per share to \$72.00 per share, which was a drop of 8.9%. On the next trading day, December 27, the stock dropped another 4.3% to \$68.90. See Declaration of Wallace Showman ("Showman Decl.") Ex. A.

### **III. ReNu with MoistureLoc**

#### **A. Hong Kong Incidents**

B&L received clearance from the U.S. Food and Drug Administration ("FDA") for a new contact lens solution called MoistureLoc in May 2004. At its July 29, 2004 conference call, Zarrella indicated that when

Moistureloc is introduced into the market in September it should further strengthen B&L's position. During the first half of 2005, Zarrella emphasized that Moistureloc would yield high margins and cash flow and presented a great opportunity to increase market share.

According to the Complaint, on October 20, 2005, the Hong Kong Department of Health ("HKDH") sent an e-mail to B&L requesting that B&L investigate whether there was a casual relationship between its ReNu products and keratitis<sup>11</sup> because of the HKDH's observations of a rising trend of keratitis among users of ReNu products. B&L failed to respond to the October 20 notification and the reason for this was because the employee to whom the e-mail was addressed was no longer with B&L. See Shin Aff. Ex. 15.<sup>12</sup> On November 11, 2005, another B&L employee received an e-mail from the HKDH stating that "a rising trend for hospital admission due to CL [contact lens] related keratitis was observed from June to September 2005, with the peak in August 2005." See Shin Aff. Ex. 15. The e-mail stated that out of 62 keratitis patients interviewed, 40% reported using a B&L ReNu lens solution, and seven of those showed signs of a Fusarium infection. The HKDH provided lot numbers for the ReNu bottles that could be recovered from the patients and stated it would be "grateful if [B&L] could conduct an investigation based on the information provided to see if there is any

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<sup>11</sup>The Complaint states that according to the FDA, Fungal keratitis is a severe infection of the cornea caused by the Fusarium fungus. Patients who do not respond to antifungal medications can experience vision loss, which usually requires surgical intervention.

<sup>12</sup>Plaintiffs argue that the e-mail document is not incorporated in the Complaint and is not public record subject to judicial notice and accordingly the Court should not consider it.

causal relationship between the [lot numbers] and the rising trend of CL related keratitis." See id.

In response to HKDH's request, B&L filed a Medical Device Report ("MDR") on the Hong Kong cases with the FDA within 30 days as required by FDA regulations. See 21 C.F.R. §803.10.<sup>13</sup> After conducting research on the identified lots, B&L informed HKDH in a letter that it had reviewed its manufacturing batch records and found nothing unusual, and that it had tested retained samples from the identified lots and discovered that they met product specifications. As indicated in the letter, the evidence suggested that the incidents were not attributable to B&L's product and noted that B&L's market share in Hong Kong could explain the percentage of the affected patients who reported using B&L products. In a February 2006 press release, the Hong Kong health authorities stated that "Sterility tests performed by the [Center for Health Protection] for samples of the products from the local market were also negative for fungal infections." Further, the press release noted that the number of fungal keratitis cases admitted to local hospitals had stabilized since the summer.

Plaintiffs allege that during this time B&L continued to make public statements affirming the safety, efficacy and commercial success of MoistureLoc, without disclosing the facts regarding the incidents in Hong Kong. For instance, on October 26, 2005, Zarrella touted Moistureloc's commercial success in Asia. In addition, B&L announced on November 29, 2005 that the FDA cleared additional labeling claims for

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<sup>13</sup>The FDA received the MDR from B&L reporting the details of the Hong Kong incidents on Dec. 8, 2005.

MoistureLoc, stating "As our clinical data show, ReNu with MoistureLoc solution ... delivers sustained comfort and resists protein uptake while providing excellent disinfection for soft contact lenses." Moreover, in January 2006, Zarrella again touted the commercial success of MoistureLoc and stated that B&L would use the product's formula in a new dry eye product before the end of 2006.

### **B. Singapore Cases**

On February 17, 2006, the Singapore Ministry of Hospitals ("SMOH") advised B&L of a spike in Fusarium cases involving MoistureLoc users.<sup>14</sup> On the same day, the SMOH issued a press release publicly reporting these observations and advising "contact lens users to discontinue using Bausch & Lomb's ReNu multipurpose contact lens solution for the time being[.]" On February 22, 2006, the SMOH noted in a press release that a "significant number of patients had a history of poor contact lens practice," that the findings "indicate association rather than causation," and that "[f]urther investigations are underway to establish the cause of the infection." Based on the Singapore report, the HKDH re-opened their investigation. Within days, B&L voluntarily suspended sales of all ReNu products, including MoistureLoc, in Singapore and Hong Kong and issued a press release on February 22, 2006 disclosing the "unprecedented outbreak of fungal keratitis in Singapore," "the unusually high number" of cases in Singapore, and B&L's voluntary suspension of sales in Singapore and Hong Kong. In

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<sup>14</sup>Plaintiffs also allege that the FDA later determined that B&L failed to timely send in an MDR report to the FDA regarding the Singapore information that suggested that its ReNu contact lens solution may have caused or contributed to death or serious injury.

addition, B&L indicated that it had not received Fusarium keratitis reports elsewhere in the world and continued to sell MoistureLoc in all markets except Singapore and Hong Kong.<sup>15</sup>

### **C. Incidents Outside Asia**

In March 2006 the first reports of Fusarium infections in contact lens wearers outside Asia were reported in the U.S.<sup>16</sup> Following these reports, B&L carried out an investigation to determine the cause of the infections, which involved numerous tests, millions of dollars and collaboration with government agencies, health authorities and independent experts.<sup>17</sup> B&L publicly disclosed the investigation and its cooperation with the CDC in a March 31, 2006 press release. Plaintiffs allege that B&L failed to disclose the known facts regarding the outbreak and instead confirmed in the press release that it believed that "the root cause of these infections is not related to a specific contact lens or lens product" and insisted that "ReNu multi-purpose solutions have unsurpassed disinfecting efficacy against Fusarium as well as other known ocular pathogens." Moreover, plaintiffs contend that rather than disclosing the link between Fusarium keratitis and MoistureLoc, B&L blamed "poor patient compliance with lens care regimens and contact lens wear." However, B&L claims that the same day

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<sup>15</sup>According to plaintiffs, the press release did not disclose the fact that forty-six out of fifty-five patients in Hong Kong and Singapore with keratitis had used ReNu products and continued to deny any relationship between ReNu and keratitis, noting that the "cause of the outbreak is still to be determined."

<sup>16</sup>An ophthalmologist in New Jersey sent a report to the U.S. Centers for Disease Control and Prevention ("CDC") regarding patients he witnessed with Fusarium keratitis associated with contact lenses.

<sup>17</sup>The CDC also began an investigation and in conjunction with the Johns Hopkins Wilmer Eye Institute, implemented a surveillance program to investigate and track the incidence of keratitis in the U.S.



as the March 31 press release, the press reported that "Benjamin Park, a CDC epidemiologist, said there was 'no evidence to suggest that there's a particular product that's involved.'" See Shin Aff. Ex. 23.

On April 10, 2006, the CDC publicly announced that it had been investigating 109 *Fusarium keratitis* cases in the U.S. The CDC also called on doctors to report any *Fusarium* cases and noted that it was trying "to determine whether this cluster represents an increase of *Fusarium keratitis* infections and to determine the association, if any, of these cases with any product." See Shin Aff. Ex. 24. In addition, the same CDC press release reported that, of 30 patients for whom complete data was available, 26 remembered which solution they used during the month prior to their infections and that 26 patients reported using a ReNu solution. However, on the same day, in an FDA press release, an FDA director noted that "[i]t is important to note that some of the affected patients had used other solutions in addition to the ReNu brand, and that the source of this fungus has not yet been identified. But we're working with CDC and Bausch & Lomb - and we're investigating other possible causes - to prevent these infections.'" See Shin Aff. Ex. 26.

That same day, B&L announced that it was suspending shipments from the Greenville, South Carolina plant that manufactured the MoistureLoc sold in the U.S., Singapore and Hong Kong pending completion of the investigation. In addition, major retailers including Wal-Mart, Rite Aid, Walgreens and Eckerd's pulled the product from their shelves the next day. According to the Complaint, analysts were in agreement that

these events signaled bad news for B&L's revenues and earnings. However, during an April 11, 2006 interview, the FDA's Acting Commissioner confirmed that B&L's action was voluntary, stating that "[t]here is not yet enough evidence to suspend the use of the product or to withdraw it." See Shin Aff. Ex. 26.

Plaintiffs allege that in a conference call on April 12, 2006 Zarrella continued to deny a causal link between MoistureLoc and Fusarium keratitis, despite a report from the SMOH on the same day indicating that it had found a "strong association between corneal infection and the use of ReNu solution," even after considerations of factors such as socio-demographic, lens, hygiene and environment, and that the "findings were also consistent with recent observations made in the US and Hong Kong." On the same day, B&L's stock price dropped another \$3.42 per share, or 7% closing at \$45.61. On April 13, 2006, B&L withdrew MoistureLoc from the U.S. market.

On May 3, 2006, one day after the CDC released preliminary data from its investigation, B&L issued a press release reporting that in the cases analyzed to date by the CDC, the percentage of patients who used MoistureLoc was disproportionate to B&L's market share. However, even after these findings, in a press release dated May 5, 2006, the CDC cautioned that "patients ha[d] reported using multiple products, including those manufactured by [B&L], Alcon and Advanced Medical Optics, Inc. At this point, it is too early in the investigation to say whether a particular product or solution may be responsible for the outbreak." See Shin Aff. Ex. 27. On May 15, 2006, B&L announced that

its internal investigation ruled out contamination and other possible causes of the reported Fusarium cases. See Shin Aff. Ex 22. It also concluded that some aspect of the MoistureLoc formula increased the risk of Fusarium infection in unusual circumstances. On the same day, B&L announced a permanent global recall of MoistureLoc. In addition, the FDA announced on May 16, 2006 that it had completed an inspection of B&L's Greenville, SC plant begun in March and, while preliminarily finding deviations from quality systems regulations, indicated that they did not support a correlation between MoistureLoc and the Fusarium infections.<sup>18</sup> See Shin Aff. Ex. 28.

## **DISCUSSION**

### **I. Defendants' Motion to Dismiss**

As with any complaint, when deciding a motion to dismiss a securities fraud claim, the court must accept the plaintiffs' factual allegations as true and must draw all inferences in the plaintiffs' favor. See Ganino v. Citizens Utilities Co., 228 F.3d 154, 161 (2d Cir.2000); see also Scheuer v. Rhodes, 416 U.S. 232, 236 (1974). Nonetheless, "factual allegations must be enough to raise a right of relief above the speculative level, on the assumption that all of the allegations in the complaint are true." See Bell Atl. Corp. v. Twombly,

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<sup>18</sup>The CDC published the final report on its Fusarium investigation in the Journal of the American Medical Association on August 23, 2006. See Shin Aff. Ex. 29. The report found that the Fusarium infections were not the result of any defect in the manufacturing process or of any contamination at Greenville or any other B&L facility. See id. The CDC found that "exposure to Fusarium was likely the result of extrinsic contamination of contact lens solution bottles or lens cases during outside of the manufacturing or storage processes, perhaps in patients' homes." See id. In addition, the report stated that "the [MoistureLoc] formulation meets all current biocidal standards against Fusarium." See id. The researchers concluded that the infections "may have been caused by a complex and, as yet, undetermined interaction between MoistureLoc, Fusarium, and possibly the lens case or contact lens." See id.

---U.S. ----, 127 S.Ct. 1955, 1965 (2007) (requiring plaintiff to plead "enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of [their claims]"); see also ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 98 (2d Cir.2007) ("We have declined to read Twombly's flexible 'plausibility standard' as relating only to antitrust cases.").

The purpose of a motion to dismiss is "to assess the legal feasibility of the complaint, not to assay the weight of the evidence which might be offered in support thereof." See Geisler v. Petrocelli, 616 F.2d 636, 639 (2d Cir.1980). The court's inquiry "is not whether the plaintiff will prevail, but whether the plaintiff is entitled to offer evidence to support his claims." See United States v. Yale New Haven Hosp., 727 F.Supp. 784, 786 (D.Conn.1990), quoted in In re Xerox Corp. Erisa Litigation, 483 F.Supp.2d 206 (D.Conn. April 17, 2007).

In making this inquiry, the court may consider the facts stated on the face of the complaint, as well as in documents appended to the complaint or incorporated in the complaint by reference, and matters of which judicial notice may be taken. See Leonard F. v. Israel Discount Bank of N.Y., 199 F.3d 99, 107 (2d Cir.1999). This includes, in securities fraud actions, "public disclosure documents required by law to be filed, and actually filed, with the SEC...." See Kramer v. Time Warner, Inc., 937 F.2d 767, 774 (2d Cir.1991); Rushing v. Nexpress Solutions, Inc., 2006 WL 2640645, at \*3 (W.D.N.Y. September 14, 2006).

While the pleading rules in federal court require only "a short and plain statement" of the plaintiff's claim for relief, Fed.R.Civ.P.

8, allegations of fraud must be "stated with particularity." See Fed.R.Civ.P. 9(b). In the context of a civil action for securities fraud, this particularity requirement has been expanded by the PSLRA. See 15 U.S.C. § 78u-4. Because plaintiffs' Rule 10b-5(b) claim requires a showing of scienter, it is subject to the heightened pleading requirements of the PSLRA, which requires plaintiffs "to state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." See id.

In Tellabs, Inc. v. Makor Issues & Rights, Ltd., --- U.S. ---, 127 S.Ct. 2499 (2007), the Supreme Court established the following procedure that a court must follow when faced with a Rule 12(b)(6) motion to dismiss a Section 10(b) action. First, the court must accept all factual allegations in the complaint as true and must also consider other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions, "in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." See id. at 2509. Then, to determine whether the facts in the complaint and in these other sources give rise to a strong inference of scienter, the court must ask whether "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." See id. at 2510. The court must be careful to consider whether "all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." See id. at 2509 (emphasis in original).

## **II. Judicial Notice and the Facts and Documents at Issue**

Defendants contend that plaintiffs' allegations related to whether B&L cooperated with public health officials in its response to the *Fusarium keratitis* infections are untenable because defendants did cooperate with public health officials as seen through the chain of e-mails dated October 20, 2005 and November 11, 2005. See Shin. Aff. Ex. 15. In addition, defendants proffered the transcript of a TV interview dated April 11, 2006 during which the Acting Commissioner of the FDA stated "there is not yet enough evidence to suspend the use of the product or to withdraw it" to show efforts by B&L that defendants claim should be considered in determining whether the Complaint adequately pleads a strong inference of scienter. See Shin Aff. Ex. 26. Plaintiffs argue that the Court should not consider defendants' proffer because the Complaint makes no reference to the October 20, 2005 and November 11, 2005 e-mails. In addition, plaintiffs contend that it is inappropriate, when deciding a motion to dismiss, for the Court to consider the Acting Commissioner of the FDA's statement during an April 11, 2006 video interview.

Because defendants' argument regarding whether their cooperation with public health authorities was properly disclosed hinges on whether the Court may consider the e-mails at issue (Ex. 15) and the video interview transcript in question (Ex. 26), the Court must first determine whether such exhibits may be considered in determining a motion to dismiss.

A court reviewing a motion to dismiss a securities fraud claim may take judicial notice of and consider the contents of documents that are required by law to be filed with the SEC, as well as other documents integral to and explicitly relied on in the complaint, including the full text of documents that are partially quoted. See Rothman v. Gregor, 220 F3d 81, 88 (2d Cir. 2000); Chambers, 282 F3d at 153; In re Bausch & Lomb, Inc. Sec. Litig., 2003 WL 23101782 at \*17 (W.D.N.Y. 2003). However, such documents may not be considered to establish the truth of the matters asserted in them. See Kramer v. Time Warner, Inc., 937 F.2d 767, 774 (2d Cir. 1991).

Here, the Complaint makes no specific reference to the e-mail chains dated October 20, 2005 and November 11, 2005 sent to B&L, nor are the e-mails attached to the Complaint. However, the Court finds that the Complaint does incorporate these documents since they relate to the very e-mail notices sent by the HKDH authorities to B&L that plaintiffs repeatedly cite and characterize in various paragraphs of their Complaint. See Complaint at ¶¶ 111, 124, 125, 162 n.15 and 183(a).<sup>19</sup> Thus, the Court finds that the documents relied by B&L in their exhibit 15 are "integral to and explicitly relied on in the Complaint." Accordingly, the Court will consider the e-mail chains dated October 20 and November 11, 2005 as found in B&L's exhibit 15.

With respect to the video interview transcript dated April 11, 2006, the Complaint makes no reference to the transcript. The Court

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<sup>19</sup>For example, ¶ 125 states "After B&L failed to respond to the HKDH's October 20, 2005 notification, health officials at the HKDH issued a second formal notice to B&L about a potential link between the outbreak of keratitis and *ReNu with MoistureLoc* on November 11, 2005."

nonetheless concludes that consideration of the April 11, 2006 transcript is appropriate. Defendants seek to use exhibit 26 to show inferences of defendants' non-culpable conduct. Defendants contend that under Tellab this is proper since that Court there held that a court must consider both culpable and non-culpable inferences for defendants' conduct. To show inference of defendants culpable conduct, plaintiffs allege in the Complaint that on April 10, 2006, the CDC publicly announced that it had been investigating 109 *Fusarium keratitis* cases in the U.S. Moreover, plaintiffs allege that in a conference call on April 12, 2006 Zarrella continued to deny a causal link between MoistureLoc and *Fusarium keratitis*. Defendants' attempt to show inference of non-culpable conduct involved the inclusion of the video interview transcript of the acting Commissioner of the FDA on April 11, 2006. See Shin Aff. Ex. 26. The Court finds that defendants' use of exhibit 26 is proper in considering a motion to dismiss. Under the Tellabs case, efforts by B&L as shown by the April 11, 2006 video interview transcript, are proper when determining whether the Complaint adequately pleads a strong inference of scienter. See Tellabs, --- U.S. ---, 127 S.Ct. 2499, Pugh v. Tribune Co., 521 F.3d 686, 695 (7th Cir. 2008).<sup>20</sup> Therefore, the Court will consider the April 11, 2006 video

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<sup>20</sup>In addition, the Court may consider "facts of which judicial notice may properly be taken under Rule 201 of the Federal Rules of Evidence." See In re Tower Auto.Sec. Litig., 483 F.Supp.2d 327, 334 (S.D.N.Y. 2007) citing In re Merrill Lynch & Co., Inc., 273 F.Supp.2d 351, 356-357 (S.D.N.Y.2003). Here, plaintiffs do not dispute the accuracy of the transcript, but rather contend only that it is not a public record and was not relied upon in framing the complaint. The courts, however, have considered similar statements by government officials to the press. See Johnston v. Nuclear Regulatory Comm'n, 766 F2d 1182, 1189 n.6 (7th Cir. 1985).



interview transcript as evidence in considering whether the Complaint adequately pleads a strong inference of scienter.

### **III. Accounting Matters**

#### **A. Failure to Allege Scienter**

Plaintiffs' Section 10(b) claim must allege that the defendants acted with scienter. See Novak v. Kasaks, 216 F.3d 300, 306 (2d Cir.2000). The PSLRA requires that the complaint "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). "[I]n determining whether the pleaded facts give rise to a 'strong' inference of scienter, the court must take into account plausible opposing inferences." See Tellabs, 127 S.Ct. at 2510. For an inference of scienter to be strong, "a reasonable person [must] deem [it] cogent and at least as compelling as any opposing inference one could draw from the facts alleged." See id. "The inquiry ... is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." See id. at 2509 (emphasis in original). Accordingly, to state a claim for a violation of Section 10(b) of the Exchange Act and Rule 10b-5, a plaintiff must allege, inter alia, that a defendant made misstatements or omissions of material fact with scienter. See Lentell v. Merrill Lynch & Co., Inc., 396 F.3d 161, 172 (2d Cir.2005). "Scienter, as used in connection with the securities fraud statutes, means intent to deceive, manipulate, or

defraud or at least knowing misconduct." See SEC v. First Jersey Sec., Inc., 101 F.3d 1450, 1467 (2d Cir.1996).

A plaintiff can establish a strong inference of fraudulent intent in two ways: "either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." See Shields v. Citytrust Bancorp, Inc., 25 F.3d 1124, 1128 (2d Cir.1994); San Leandro Emergency Med. Group Profit Sharing Plan v. Philip Morris Cos., 75 F.3d 801, 813 (2d Cir.1996); Acito v. IMCERA Group, Inc., 47 F.3d 47, 52 (2d Cir.1995).<sup>21</sup> "[A]n allegation that defendants were motivated by a desire to maintain or increase executive compensation is insufficient because such a desire can be imputed to all corporate officers." See Kalnit v. Eichler, 264 F.3d 131, 140 (2d Cir.2001). "It is well established that boilerplate allegations that defendants knew or should have known of fraudulent conduct based solely on their board membership or executive positions are insufficient to plead scienter." See In re Sotheby's Holdings, Inc., 2000 WL 1234601, at \*7 (S.D.N.Y. 2000); see also In re Winstar Commc'ns, 2006 WL 473885, at \*7 (S.D.N.Y. Feb. 2006).

"In addition to actual intent...recklessness is a sufficiently culpable mental state in the securities fraud context." See Dynex, 2008 WL 2521676, at \*3. Recklessness requires a showing of "reckless

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<sup>21</sup>In addition, a plaintiff may establish scienter by showing that defendants: "(1) benefitted in a concrete and personal way from the purported fraud; (2) engaged in deliberately illegal behavior; (3) knew facts or had access to information suggesting that their public statements were not accurate; or (4) failed to check information they had a duty to monitor." See Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc., 531 F.3d 190, 2008 WL 2521676, at \*3 (2d Cir. 2008) (quoting Novak, 216 F.3d at 311).

disregard for the truth, that is, conduct which is highly unreasonable and which represents extreme departure from standards of ordinary care." See SEC v. McNulty, 137 F.3d 732, 741 (2d Cir.1998). "[A]n allegation that a defendant merely 'ought to have known' is not sufficient to allege recklessness." See Hart v. Internet Wire, Inc., 145 F.Supp.2d 360, 368 (S.D.N.Y.2001) (quoting Troyer v. Karcagi, 476 F.Supp. 1142, 1152 (S.D.N.Y.1979)); see also In re Bayou Hedge Fund Litig., 534 F.Supp.2d 405, 415 (S.D.N.Y. 2007). Even an "egregious failure to gather information will not establish 10b-5 liability as long as the defendants did not deliberately shut their eyes to the facts." See Hart, 145 F.Supp.2d at 368-69 (internal quotation marks and citations omitted).

### **1. Recklessness**

With these standards in mind, the allegations supporting scienter must be considered. B&L contends that because plaintiffs have alleged no facts establishing that any of the individual defendants was personally aware of any problem at any of B&L's foreign subsidiaries before the Audit Committee's investigations and nor do plaintiffs allege that any one of the affected subsidiaries was so large or central to B&L's business that B&L and the individual defendants were reckless to rely on the subsidiaries' financial reporting, especially in light of the clean audit opinions handed down year after year by PwC, plaintiffs have failed to satisfy the intent to defraud, or scienter requirement and therefore have failed to state a §10(b) claim. Plaintiffs, on the other hand, argue that they adequately pleaded

scienter by pleading the existence of various red flags that B&L recklessly disregarded. Plaintiffs allege that the subsidiaries' revenue recognition and other specific accounting practices were improper and contrary to B&L's own policies as well as the specific amounts by which those practices falsified B&L's financial statements. The Complaint also alleges facts, including the subsidiaries' overriding of internal controls and channel stuffing, from which an inference of scienter is at least as likely as an inference of innocence or mere negligence. This Court agrees with B&L. The mere fact that B&L's financial reporting was inaccurate does not establish scienter.

After a thorough review of the Complaint and the exhibits incorporated by reference, the Court concludes that scienter is not adequately pleaded. There are no factual allegations to support plaintiffs' conclusory charges. Plaintiffs have not identified any communication or report received by any individual defendant raising a red or yellow flag about the foreign subsidiaries' accounting prior to the publicly disclosed Audit Committee investigations. Nor do plaintiffs offer any particularized allegation of an inference that management's assessment of internal controls as of December 2004 and the related CEO and CFO certifications pursuant to the Sarbanes-Oxley Act were not honestly and reasonably believed to be true when made. This is accentuated by the report of PwC, which had conducted its own review before the BLIO allegations became known.

It is noteworthy that B&L's outside auditor's did not question B&L's accounting practices. See Kushner v. Beverly Enters., Inc., 317 F.3d 820, 829 (8th Cir. 2003).<sup>22</sup> Based on PwC's review, it concluded that management's assessment was fair and that B&L's internal controls were effective. The Complaint alleges no facts that would allow an inference that PwC's review was inadequate, that B&L's management kept any information from PwC, or that PwC had any incentive to give a false audit report. Rather, plaintiffs simply allege that B&L and its senior officers "must have known" in advance about the various foreign subsidiary accounting issues that were later uncovered due to the investigation performed by B&L. However, allegations of accounting improprieties at a subsidiary are not enough to demonstrate scienter by a parent corporation and its officers. See Chill v. Gen. Elec. Co., 101 F.3d 263, 270-71 (2d Cir. 1996); see also Higginbotham v. Baxter, Int'l., Inc., 496 F3d 753, 758 (7th Cir. 2007) (foreign subsidiary's fraud does not establish scienter on the part of the parent company and its officers).

The Complaint also relies on confidential sources to boost its scienter allegations. CW1 asserts that B&L or the Individual Defendants were alerted to and knew of the violations of the company's accounting policies because employees within the BLIO division informed them of such violations and the Individual Defendants thus had access to this information.

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<sup>22</sup>Plaintiffs do not allege a single fact contradicting that PwC had previously conducted independent audits of B&L and found that its financial statements "presented fairly, in all material respects," the financial position of the company and its consolidated subsidiaries, in conformity with GAAP.

A complaint may rely on confidential sources as long as the facts alleged "provide an adequate basis for believing that the defendants' statements were false." See Novak, 216 F.3d at 314. In addition, the confidential sources must be "described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." See id. at 300. While the Court of Appeals has not addressed the weight to be afforded allegations based on confidential sources in light of Tellabs, the Seventh Circuit held after Telllabs that "allegations from confidential witnesses must be discounted" because "[i]t is hard to see how information from anonymous sources could be deemed compelling or how we could take account of plausible opposing inferences. Perhaps these confidential sources have axes to grind. Perhaps they are lying. Perhaps they don't even exist." See Higginbotham, 495 F.3d at 757. However, several district courts in this circuit have considered allegations based on confidential sources after Telllabs without discounting them. See e.g., City of Brockton Ret. Sys. v. Shaw Group Inc., 540 F.Supp.2d 464, 474 (S.D.N.Y.2008) (declining to adopt the Higginbotham standard); In re Xethanol Corp. Secs. Litig., 2007 WL 2572088, at \*3, n. 3 (S.D.N.Y.2007) (descriptions of confidential sources were sufficient to allow the court "to infer that the witnesses are likely to possess the information contained in their statements").

Here, neither of the two confidential sources specifically state that any Individual Defendant had direct information or access to

information of BLIO's illegal practices or that it was violating GAAP, or that it contradicted the company's financial statements. See, e.g., Shaw Group, 540 F.Supp.2d at 474 (allegations based on confidential sources did not establish scienter where they did not show that defendants had information regarding accounting irregularities). As defendants note, CW1 vaguely refers to unspecified periodic reports made to unnamed "regional and senior managers" and alleges that two "lawyers in B&L's Rochester, New York, legal department" knew of provisions in BLIO's charter, which were relied on by BLIO to trade in tax credits. However, CW1 does not allege that the two lawyers were ever told that BLIO would rely upon those provisions to trade in tax credits or that such trading was improper. In addition, absent from CW1's story are allegations that any of the Individual Defendants were personally involved in or had knowledge of any of the improper practices in Brazil or that any of the accounting issues were "ever passed up the chain of command" to the Individual Defendants themselves. See In re Alpharma Inc., Sec. Litig., 372 F3d 137, 151 (3d Cir. 2004). Plaintiffs have also failed to allege any facts showing that the confidential sources - BLIO's former general manager who was terminated by B&L and CW2 a former BLIO internal auditor - had any contact with the Individual Defendants or would have knowledge of what they knew or should have known during the Class Period.<sup>23</sup> See, e.g., In re Elan Corp. Secs. Litig., 543 F.Supp.2d 187, 219 (S.D.N.Y.2008)

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<sup>23</sup>The Complaint alleges that CW2 reported to "local officers" rather than "directly reporting only to B&L's Rochester office." In denying that Rochester officials had direct access to CW2's audit work at BLIO, plaintiffs strengthen the opposing inference that B&L senior management did not know about the problems at BLIO.

(allegations based on confidential sources were insufficient to establish scienter where there were no facts to establish that the confidential sources would have known what information was communicated to senior executives); see also Malin v. XL Capital Ltd., 499 F.Supp.2d 117, 141 (D.Conn.2007) (statements by confidential sources that accounting deficiencies were well known were insufficient to establish scienter).

In sum, plaintiffs do not proffer concrete evidence that anyone at B&L's headquarters in Rochester knew of the irregularities in Brazil until a BLIO employee reported the misconduct of local managers in Brazil to B&L's senior management in Rochester, NY pursuant to the company's established whistleblower program. Soon thereafter, B&L's Audit Committee immediately launched a massive independent investigation into BLIO. In addition, B&L voluntarily reported the matter to the SEC and announced it to the public. Subsequently, the Audit Committee found that no one outside BLIO was aware of or involved in the misconduct in Brazil. Moreover, when the disclosures relating to the Brazilian subsidiary was revealed, Zarrella reminded all employees to report any possible violations of company policies immediately. Employees in Korea also responded by alerting B&L management to possible issues in BL Korea. Furthermore, the Audit Committee investigated accounting issues at BL Korea and promptly revealed its inquiry to the public and informed the SEC. Finally, on its own initiative, B&L undertook an expanded review of revenue recognition practices at other foreign subsidiaries and other accounting matters



and publicly disclosed the results of the review in regular filings with the SEC and ultimately in the restated financial earnings. Thus, the fact that the accounting improprieties occurred at B&L's foreign subsidiaries, the Court finds that this does not raise a strong inference of scienter against B&L or the Individual Defendants.

## **2. Motive and Opportunity to Commit Fraud**

It is undisputed that the defendants in this case had a clear opportunity for committing fraud. They comprised the senior management of B&L during the Class Period and had ample opportunity to manipulate the stock market's valuation of the company's stock. What is at issue, however, is whether plaintiffs' complaint adequately alleges that defendants had the requisite motive for committing fraud. "Motive ... entail[s] concrete benefits that could be realized by one or more of the false statements and wrongful nondisclosures alleged." See Shields, 25 F.3d at 1130. To make this showing, plaintiffs rely on the favorable sales of B&L stock by the Individual Defendants during the Class Period. These defendants, in contrast, argue that their sales of company stock during the Class Period are insufficient to support a fraud claim. Defendants next assert that plaintiffs have failed to properly allege scienter because the facts set forth in the Complaint, when considered in the context of the full stock transactions that occurred within the Class Period, do not show that defendants had the requisite scienter to sustain a securities fraud action. According to the Complaint and the SEC disclosure documents upon which it is based, the defendants engaged in a number of stock transactions during the

Class Period. Defendants argue that the pattern of sales and purchases by the Individual Defendants can only be interpreted as innocent trading and cannot, as a matter of law, support the scienter element of a securities fraud claim. Plaintiffs respond that the volume of stock sales and the size of the Individual Defendants' profits from these sales creates the inference of fraudulent motive necessary to survive a motion to dismiss.

The motive-and-opportunity prong of scienter, which plaintiffs claim applies to the Individual Defendants, requires allegations of "concrete benefits that could be realized by one or more of the false statements and wrongful disclosures alleged." See Novak, 216 F.3d at 307; see also Rothman, 220 F.3d at 93. "Motives that are generally possessed by most corporate directors and officers do not suffice; instead, plaintiffs must assert a concrete and personal benefit to the individual defendants resulting from the fraud." See Kalnit, 264 F.3d at 139. "The mere fact that insider stock sales occurred does not suffice to establish scienter." See Shaw v. Digital Equipment Corp., 82 F.3d 1194, 1224 (1st Cir.1996). To create an inference of scienter through the stock sales of insiders, plaintiffs must establish that the stock sales during the class period were "suspicious" or "unusual." See Acito, 47 F.3d at 54 (holding that scienter was insufficiently pleaded because stock sale by single insider was not "unusual"); Ressler v. Liz Claiborne, Inc., 75 F.Supp.2d 43, 58 (E.D.N.Y. 1998), aff'd, 1999 WL 568023 (2d Cir.1999). In evaluating whether a stock transaction is so "unusual" as to support an inference

of motive, the court assumes that "the defendant is acting in his or her informed economic self-interest." See Shields, 25 F.3d at 1130.

The central question, then, is whether the stock transactions in question were so "suspicious" or "unusual" as to give rise to the strong inference of fraudulent intent. Here, the Individual Defendants made substantial sales in the quarters preceding the Class Period. The sales in which the Individual Defendants engaged during the Class Period adhered to a pattern and were made at regular intervals as part of preset trading plans under Rule 10b5-1. See Shin Aff Ex 31. Accordingly, these stock sales alleged do not appear to be "unusual" in either their amount or their timing. See Fishbaum v. Liz Claiborne, Inc., 1999 WL 568023, at \*4 (2d Cir.1999) (Sales made under "a periodic divestment plan" of this kind do not raise an inference of improper trading); In re IAC/InterActiveCorp Sec. Litig., 478 F.Supp.2d 574, 604 (S.D.N.Y. 2007) (trades under 10b5-1 plan "do not raise a strong inference of scienter").

The timing of a transaction is unusual or suspicious when its timing is "calculated to maximize personal benefit from inside information." See In re Apple Computer Secs. Litig., 886 F.2d 1109, 1117 (9th Cir. 1989) (citing Lilly v. State Teachers Retirement Sys., 608 F.2d 55, 56 (2d Cir.1979); SEC v. Musella, 578 F.Supp. 425, 441 (S.D.N.Y.1984); Jefferies & Co. v. Arkus-Duntov, 357 F.Supp. 1206 (S.D.N.Y.1973)). Applying this standard, the timing of the defendants' stock transactions cannot be considered unusual. As an initial matter, the timing of the sales did not closely coincide with any of the

alleged false comments, such that the Court could infer that the Individual Defendants sought to reap the immediate benefit a falsely positive statement would have on the market. According to the Complaint, defendants Zarrella, McCluski and Hahs stopped selling shares more than two months *before* the first disclosure of accounting problems in Brazil; over 80% of defendant Loughlin's sales were made more than two months before the first disclosure; defendant Stiles stopped selling shares four months before the first disclosure; defendant Ide stopped selling more than five months before and defendant Panzarella stopped selling more than seven months before. See Comp. ¶ 199.<sup>24</sup>

The Court further notes that the stock sales at issue took place, for the most part, over two months prior to the release of the negative disclosure by B&L relating to its accounting problems. Such timing does not suggest that the Individual Defendants meant to realize profits immediately prior to an expected and dramatic fall in the stock's price. Further, plaintiffs do not explain how the timing of these sales could be viewed as suspect. In fact, the law in this Circuit is clear that they are not and that stock sales are not indicative of scienter when they are "more than two months before the announcement" in question. See Malin, 499 F.Supp.2d at 154 n.24; see also In re KeySpan Corp. Sec. Litig., 383 F.Supp.2d 358, 385 (E.D.N.Y. 2003) (sales two months before disclosure insufficient). The Court

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<sup>24</sup>Well over half of the sales were made more than eight months prior to the first alleged corrective disclosure; 81% were made more than five months before; and virtually all (97%) of the sales were made more than two months before the first disclosure of accounting problems. See Shin Aff Ex. 31.

concludes that the stock sales at issue, being remote in time from any misstatements and in amounts that do not necessarily support a claim of fraud, were not unusual or suspicious and therefore do not demonstrate that defendants had a motive to commit fraud.<sup>25</sup> Consequently, the plaintiffs have not properly pleaded scienter by establishing defendants' motive and opportunity to commit fraud.

### **3. Scienter as alleged against B&L's Asian subsidiaries**

Plaintiffs assert that the Complaint alleges specific admissions by B&L that the subsidiaries intentionally engaged in fraudulent accounting. See Pl. Br. at 26. Plaintiffs do not cite to specific admissions by B&L but instead point to disclosures that various practices at certain subsidiaries were improper or violated company policy. See id. at 26-27. Essentially, plaintiffs allege that B&L's subsidiaries and joint ventures in China, India, Korea and Japan engaged in improper accounting practices. Moreover, plaintiffs contend that sales practices in BL Korea amounted to "channel stuffing." See id. at 27. As an initial matter, "channel stuffing is not fraudulent per se." See Garfield v. NDC Health Corp., 466 F3d 1255, 1261 (11th Cir. 2006). Courts have held that "there may be any number of legitimate reasons for attempting to achieve sales earlier. Thus, it

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<sup>25</sup>Further, since executives' equity-based compensation often includes options, these options "must be considered along with shares actually held in determining whether insider sales are significant." See In re eSpeed, Inc. Sec. Litig., 457 F.Supp.2d 266, 290 (S.D.N.Y. 2006). As the selling defendants' SEC filings show, defendants Loughlin and Ide each sold less than 20% of their equity holdings, while Stiles' equity holdings increased by 2%, McCluski's increased by 14%, Zarrella's increased by 19%, Hahs' increased by 57% and Panzarella's increased by 66%. See Shin Aff Ex. 31. In addition, the Complaint alleges no stock sales by Singh at all. These figures negate any inference of scienter sought to be drawn from stock sales during the Class period. See Fishbaum, 1999 WL 568023, at \*4 (no inference of scienter where several defendants "held more shares of Claiborne stock at the end of the class period than at the beginning").

does not support a strong inference of scienter.” See Greebel v. FTP Software, Inc., 194 F3d 185, 203 (1st Cir. 1999). Further, violations of GAAP, even ones that lead to restatement of financials, do not suffice to raise a strong inference of scienter without particularized allegations of fraudulent intent and plaintiffs offer none against B&L’s Asian subsidiaries. See In re Bristol-Myers Squibb Sec. Litig., 312 F.Supp.2d 549, 565 (S.D.N.Y. 2004). Therefore, plaintiffs’ accounting-related fraud claims against BL China, BL India, BL Korea and BL Japan do not adequately plead scienter and are dismissed.

**B. Plaintiffs’ Failure to Plead that Hahs, Ide, Singh Loughlin, Panzarella, Stiles or any of the subsidiary defendants made a relevant statement.**

To state a claim under section 10(b) and Rule 10b-5, “plaintiffs must allege that in connection with the purchase or sale of securities ... defendants made a false material misrepresentation or omitted to disclose a material information[.]” See In re Indep. Energy Holdings PLC Sec. Litig., 154 F.Supp.2d 741, 762 (S.D.N.Y. 2001) (citing Ganino, 228 F.3d at 161). In order to hold defendants Hahs, Ide, Loughlin, Panzarella, Singh, Stiles or any of the subsidiary defendants liable for securities fraud, the plaintiffs are required to plead facts claiming that these defendants made a material misrepresentation and not that others with whom they worked allegedly did so. See Stoneridge Inv. Partners, LLC v. Scientific Atlanta, Inc., 128 S.Ct. 761, 768 (2008) (necessary element of any claim under §10(b) is “a material misrepresentation or omission by the defendant”); Central Bank of Denver, N.A. v. First Interstate Bank of Denver, 511

U.S. 164, 191 (1994) (holding that the Exchange Act does not include aider and abettor liability). Here, the Complaint does not specifically allege that any of the six Individual Defendants or any of the subsidiaries made any public statements about B&L's financial results or internal controls. In addition, plaintiffs have failed to allege that any of these defendants participated in the drafting of any SEC filing or press release mentioned in the Complaint and plaintiffs do not identify any documents filed during the Class Period that attributes any specific accounting item or disclosure to them.

Plaintiffs argue that while the subsidiaries did not issue any of the statements identified in the Complaint, they can nonetheless be held liable because fraudulent sales reported by the subsidiaries were incorporated into B&L's financial statements. See Pl. Br. at 28. However, plaintiffs' argument presumes that they have adequately plead the scienter requirement on the part of the subsidiaries. As discussed in Point III.A.1 and 2, plaintiffs have failed to do so. Given this scenario, primary liability under §10(b) will not attach simply because a subsidiary provides information to the parent company which later proves to be incorrect. See Ivers v. Keene Corp., 780 F.Supp. 185, 188 (S.D.N.Y.1991). Further, plaintiffs argue that Ide and Singh are liable because they "controlled the information" sent by BL Japan and BL India to B&L. See Pl. Br. at 27-28. However, there is no such allegation in the Complaint and even if there was, it is not enough to attribute statements in B&L's SEC filings to Ide and Singh because plaintiffs do not allege with particularity that they "participated

in the allegedly fraudulent accounting practices.” See Rosen v. Textron, Inc., 321 F.Supp.2d 308, 328 (D.R.I.2004).

### **C. Loss Causation**

To state a claim for securities fraud under §10(b) and Rule 10b-5, a plaintiff must, inter alia, plead loss causation. See Lentell, 396 F.3d at 172 (quoting First Nationwide Bank v. Gelt Funding Corp., 27 F.3d 763, 769 (2d Cir.1994)). Loss causation may not be predicated merely upon averments that the defendant’s misrepresentations inflated the purchase price of the underlying securities. See Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 347 (2005). Instead, a plaintiff can plead loss causation only by alleging that the defendant’s misstatements or omissions “concealed something from the market that, when disclosed, negatively affected the value of the security.” See Lentell, 396 F.3d at 173. In their “simplest form,” such loss causation allegations connect the diminution in stock prices to a particular corrective disclosure, “which revealed an alleged misstatement’s falsity or disclosed that allegedly material information had been omitted.” See In re AOL Time Warner, Inc. Sec. Litig., 503 F.Supp.2d 666, 677 (S.D.N.Y.2007) (citing omitted).

Here, plaintiffs identify six accounting items that B&L disclosed for the first time in SEC filings made after the Class Period ended on May 3, 2006.<sup>26</sup> Upon each of these disclosures, there was no significant diminution of the company’s share price. Indeed it only

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<sup>26</sup>Plaintiffs include claims based on (1) China sales reserves, (2) deferred tax liabilities for outside basis differences in certain foreign subsidiaries, (3) income tax related to the sale of B&L’s eye wear business, (4) B&L’s deferred compensation plan, (5) Japan litigation reserves and (6) currency translation adjustments.



moved less than 1%. Accordingly, B&L's share price did not "[f]all significantly after the truth became known" about these items. See Dura, 544 U.S. at 347. In fact, B&L's share price actually rose steadily throughout the duration of the post-Class Period disclosures from \$44.61 on May 11, 2006 to \$54.46 on February 7, 2007. See Shin Aff. Ex. 39. Plaintiffs have not adequately linked these six disclosure to a significant diminution in the price of the B&L stock. Thus, the Court finds that plaintiffs have not pleaded loss causation based on these six items. Further, the only stock price decline alleged in the Complaint to follow disclosure of any accounting issue is the price decline just after B&L's December 22, 2005 press release, which merely discussed issues in Brazil, Korea and the decision to restate financials affected by Brazil.

The relevant inquiry for loss causation purposes is whether the disclosure in question made some part of a previously undisclosed truth known. See Dura, 544 U.S. at 346-47; Lentell, 396 F.3d at 173 (to establish loss causation, plaintiffs must allege "that the misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security"). Here, plaintiffs allege no facts even remotely suggesting that the market perceived B&L's December 22, 2005 press release as revealing an "imminent" restatement of currency translation adjustments, B&L's deferred compensation plan expenses or any of the other accounting matters that were first disclosed after the Class Period. As a result, plaintiffs fail to plead loss causation as to all these matters.

Therefore, plaintiffs' accounting fraud claims are dismissed in their entirety.

#### **IV. Securities Fraud Relating to MoistureLoc**

##### **A. Allegations that Statements were Materially Misleading**

Defendants argue that plaintiffs have not plead with particularity facts sufficient to support the belief that defendants' statements were materially misleading. In particular, B&L contends that, relying solely on hindsight, plaintiffs allege defendants "must have known" that MoistureLoc would need to be withdrawn from the market as soon as it received the first report of MoistureLoc users with Fusarium from the HKDH. See Def. Br. at 29. Defendants further claim that there is a complete absence of a cogent and compelling inference that B&L knowingly or recklessly concealed material facts regarding the safety of its MoistureLoc lens solution. See Reply Br. at 15. Plaintiffs, however, contend that they have sufficiently alleged that defendants made public assurances relating to MoistureLoc that were rendered materially misleading by information known to defendants which was omitted or misrepresented. See Pl. Br. at 31.

Information is material for the purposes of §10(b) and Rule 10b-5 if there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." See Basic Inc. v. Levinson, 485 U.S. 224, 231-32, (1988);

Starr v. Georgeson S'holder, Inc., 412 F.3d 103, 110 (2d Cir.2005).<sup>27</sup>

The Second Circuit has held that information regarding a drug's adverse effects does not become material until that information "provide[s] statistically significant evidence that the ill effects may be caused by-- rather than randomly associated with--use of the drugs and are sufficiently serious and frequent to affect future earnings." See In re Carter-Wallace Sec. Litig. (Carter-Wallace I), 150 F.3d 153, 157 (2d Cir.1998); see also In re Carter-Wallace Sec. Litig. (Carter-Wallace II), 220 F.3d 36, 41 (2d Cir. 2000) ("Carter-Wallace had no sound reason to doubt the commercial viability of Felbatol or the value of its inventory until the reports of Felbatol-associated deaths became statistically significant.")

Defendants rely on Carter-Wallace and contend that they had no duty under the securities laws to disclose infection cases in Singapore and Hong Kong when it was initially reported to B&L. See Def. Br. at 30. In Carter-Wallace I, the plaintiffs alleged violations of §10(b) and Rule 10(b)(5) based on defendant drug manufacturer Carter-Wallace's allegedly misleading statements regarding adverse events associated with its epilepsy drug Felbatol. See 150 F.3d at 154. The drug was introduced in August 1993 and promoted through July 1994 as having an "unprecedented safety profile." See Carter-Wallace II, 220 F.3d at 38. In 1994, Carter-Wallace began receiving reports

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<sup>27</sup>Because "[m]ateriality is a mixed question of law and fact...a complaint may not properly be dismissed...on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance." See Ganino, 228 F.3d at 162.

of deaths from aplastic anemia, a bone marrow disease, in patients taking Felbatol. See Carter-Wallace I, 150 F.3d at 155. Carter-Wallace received one such report in January, another in March, two reports in April, two reports in May, and four reports in July. See id. On August 1, 1994, Carter-Wallace issued a "Dear Doctor" letter recommending that most patients discontinue Felbatol treatment. See id. The Second Circuit upheld the district court's dismissal of plaintiffs' §10(b) claims, stating that information regarding the aplastic anemia deaths did not become material until "Carter-Wallace had information that Felbatol had caused a statistically significant number of aplastic-anemia deaths and therefore had reason to believe that the commercial viability of Felbatol was threatened." See id. at 157. Therefore, the court held that Carter-Wallace was under no duty to disclose the Felbatol-related deaths prior to its announcement on August 1, 1994. See id.

Plaintiffs respond by arguing that statistically significant evidence of causation is not a requirement when demonstrating recklessness where "other more specific information" is known to the defendant, that the early reports from Hong Kong and Singapore provided such other "far more extensive information" and that B&L's scienter is further shown by its alleged efforts to conceal or divert public health officials' concerns. See Pls. Br. 30-32. In addition, plaintiffs contend in any event that the reported cases from Asia provided statistically significant proof of causation as of February or March 2006. See id. at 31.

One of the cases relied on by plaintiffs involving the alleged nondisclosure of information regarding adverse drug events was In re Bayer AG Sec. Litig., 2004 WL 2190357 (S.D.N.Y.2004). The adverse event at issue in that case was a condition known as rhabdomyolysis, which involves the acute breakdown of muscle tissue. See id. at \*2. In May 1998, Bayer was aware of four cases of rhabdomyolysis in patients taking Baycol. See id. In 1998 and 1999, Bayer started receiving reports of rhabdomyolysis in patients taking Baycol in combination with a drug called gemfibrozil. See id. By April 1999, Bayer had received fifty-one adverse event reports regarding rhabdomyolysis in patients taking Baycol and subsequently received sixty such reports in the last two months of that year. See id. at \*3-4. On March 10, 2000, a Bayer epidemiologist concluded that the risk of rhabdomyolysis associated with Baycol was considerably greater than that associated with other drugs of its class and that Baycol users were at a "remarkable disadvantage" relative to patients taking these other drugs. See id. at \*4. Finally, at a meeting in August 2000, Bayer's drug safety executives reached a consensus that the potential dangers associated with Baycol were "putting the brand at risk." See id. at \*4, 10.

The Bayer court stated that while Carter-Wallace I holds that isolated adverse event reports, lacking statistical significance, cannot establish that a drug is unsafe, it does not address whether such reports, supplemented by other evidence, might suffice. See id. at 9. In light of this, the district court held that Bayer's duty to

disclose information regarding the rhabdomyolysis reports arose after the August 2000 meeting because, even if causation had not been established at this time, it could be inferred that defendants viewed these issues as “sufficiently serious and frequent to affect future earnings.” See id. at \*10 (quoting Carter-Wallace I, 150 F.3d at 157). However, there was no duty to disclose this information before the consensus emerged that the rhabdomyolysis issue was putting the brand at risk. See id.<sup>28</sup>

Though Carter-Wallace I and Bayer combined materiality and scienter into a single inquiry, the Carter-Wallace I holding has implications for both elements. With respect to materiality, it stands for the proposition that isolated adverse event reports are not generally material unless and until (1) they provide evidence of an actual (i.e., statistically significant) correlation between the adverse event and the drug, and (2) the adverse events at issue are “sufficiently serious and frequent to affect future earnings.” See Carter-Wallace I, 150 F.3d at 157. However, this Court agrees with the

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<sup>28</sup>Decisions from other courts addressing similar §10(b) claims are generally consistent with Carter-Wallace I. In Oran v. Stafford, 226 F.3d 275 (3d Cir.2000), the Third Circuit affirmed the district court’s dismissal of plaintiffs’ securities fraud claims, finding that twenty-four reports of heart valve abnormalities in patients using drug combination known as “fen-phen” “suggest[ed] a link” between the adverse events and the drug but did not establish a statistically significant or “medically conclusive” relationship. See 226 F.3d at 279-80, 282-84. Therefore, these reports were not material, either alone or in combination with thirty-one similar reports in European fen-phen users. See id. at 279-80, 283-84 (“[P]laintiffs never clearly explain how the accumulation of additional anecdotal data, short of the point of statistical significance, would have added anything to the disclosure [of inconclusive adverse event data]”). In In re Intrabiotics Pharmaceuticals, Inc. Sec. Litig., 2006 WL 708594 (N.D.Cal. 2006), the plaintiffs’ complaint alleged a §10(b) violation based on the defendants’ representation that their drug was “safe and well-tolerated” in clinical trials. See 2006 WL 708594 at \*11-12. The court dismissed this claim in part because plaintiffs did not allege at what point during the clinical trials it would have been apparent that the drug was causing the adverse events at issue or when defendants became aware of this information. See id.; see also In re Alliance Pharm. Corp. Sec. Litig., 279 F.Supp.2d 171, 189 (S.D.N.Y.2003) (rejecting plaintiffs’ argument that “any undesirable results that arise during clinical testing are necessarily material,” citing Carter-Wallace I).

Bayer court that Carter-Wallace I does not establish a bright-line rule for the materiality of information regarding drug safety risks. Instead, this type of information may become material even in the absence of statistically significant evidence in light of other indications that the risk associated with adverse drug events is legitimate and serious enough to threaten drug sales.

In reviewing all the facts of this case, this Court finds that under Carter Wallace I not only was there an absence of statistically significant evidence so that B&L was under no duty to disclose reports of infections in the Fall of 2005. Also, like the hundreds of adverse reports and the preliminary assessment of relative risk in Bayer, the reports of Fusarium infections among MoistureLoc users did not make B&L's statements about MoistureLoc's safety and efficacy misleading. In addition, unlike Bayer, plaintiffs in this case have not alleged that anyone at B&L believed during the Class Period that there was a causal link between MoistureLoc and Fusarium, much less that B&L had reached an internal consensus at odds with its public statements concerning MoistureLoc's safety. Furthermore, throughout the Class Period, public health officials repeatedly stated that the cause of the infections had not been determined and that it was too early to say whether MoistureLoc or any other manufacturer's product was responsible.<sup>29</sup> In view of these facts, there is no compelling inference

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<sup>29</sup>Examples include: February 20, 2006 press release where the SMOH stated that the observed cases ... "indicate[d] association rather than causation." See Shin Aff. Ex. 21; March 31, 2006 press statement where a CDC epidemiologist stated that there was "no evidence to suggest that there's a particular product that's involved." See id. Ex. 23; April 10, 2006 press release where the FDA stated "[S]ome of the affected patients had used other solutions in addition to the ReNu brand, and that the source of this fungus had not yet been identified. But we're working with CDC and [B&L] - and we're investigating other possible causes - to prevent these infections." See id. Ex. 25; May 5,

that can be drawn that B&L had and concealed “statistically significant evidence” of a causal link with Fusarium under the Second Circuit’s Carter-Wallace decisions to show material falsity or recklessness as it relates to the statements alleged to be actionable by plaintiffs.

While plaintiffs assert that the allegedly omitted facts relating to B&L’s statements concerning Fusarium keratitis were material, allegations in the Complaint as well as controlling documents belie that claim.<sup>30</sup> MoistureLoc was required to meet stringent FDA tests for efficacy against the Fusarium fungus before it was cleared for sale to the public in 2004. In the Fall of 2005, more than a year after its release, B&L received non-specific reports of eye infections among contact lens wearers in Hong Kong, most of which did not involve users of its products and did not involve infections due to Fusarium. After reporting these cases to the FDA and following up with the HKDH, B&L did not receive additional reports of Fusarium infections among MoistureLoc users worldwide until February 17, 2006 when the SMOH first reported they had seen the infection there.

Plaintiffs contend that in July and August 2005, Hong Kong and Singapore officials started investigating an “unusually high” incidence of Fusarium keratitis cases. However, the earliest report

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2006 press release where the CDC advised the public that “it is too early in the investigation to say whether a particular product or solution may be responsible.” See id. Ex. 27.

<sup>30</sup>It is well established that a “Court need not accept as true any allegations that are contradicted by documents deemed to be part of the complaint, or materials amenable to judicial notice.” See In re Yukos Oil Co Sec. Litig., 2006 WL 3026024 at \*12 (S.D.N.Y.2006); see also Rapoport v. Asia Elecs. Holding Co., 88 F.Supp.2d 179, 184 (S.D.N.Y.2000)(“If these documents contradict the allegations of the...complaint, the documents control.”)



mentioned in the Complaint of infections in Hong Kong was in a press release dated August 22, 2005. See Compl. ¶123.<sup>31</sup> The press release did not report that any of the individuals had a Fusarium infection and did not mention what products they used. See Shin Aff. Ex 16. Subsequently, on October 20 and November 11, 2005, HKDH sent e-mails to B&L informing them that out of 62 keratitis patients interviewed, 40% reported using a B&L ReNu lens solution, and only seven of those showed signs of a Fusarium infection. Plaintiffs attempt to show that B&L tried to hide the seven Hong Kong cases by filing an incomplete or late report to the FDA. However, B&L filed its MDR on the Hong Kong cases with the FDA within 30 days as required by FDA regulations on December 8, 2005. Further, a comparison of the HKDH e-mail to the B&L MDR shows that it did not omit any fact recited in the e-mail. In addition, pursuant to the HKDH, B&L tested samples from the product lots at issue and found that they met specifications. Accordingly, in a February 2006 press release quoted in the Complaint, the HKDH reported that their own sterility tests yielded the same results as B&L. Thus, on the facts alleged in the Complaint, the Hong Kong cases in 2005 appeared to have been resolved and there are no facts alleged to support a "compelling" inference under Tellabs that any defendant knew or believed otherwise. See Tellabs, 127 S.Ct. at 2510.

Plaintiffs contend that B&L's mal intent may be inferred because B&L downplayed the withdrawal of products in Singapore and withheld

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<sup>31</sup>With respect to Singapore, the earliest report of Fusarium case cited in the Complaint is dated February 17, 2006 and it states that Singapore began investigating Fusarium cases in January 2006. See Compl. ¶130.

actual statistics known to them. See Pl. Br. at 31. However, within days of the reports, B&L publicly announced on February 22, 2006 that it was voluntarily suspending sales in Singapore and Hong Kong pending an investigation. Despite this candid acknowledgment, plaintiffs claim that B&L's February 22, 2006 press release denied a connection between MoistureLoc and Fusarium due to the following reasons: (1) B&L did not repeat statistics reported in a February 22 HKDH press release on the current percentage of Singapore and Hong Kong patients who used B&L products; (2) B&L stated the cause of the outbreak as "still to be determined;" and (3) B&L stated that the product was not being suspended elsewhere. See Pl. Br. at 14. However, none of plaintiffs' contentions amount to securities fraud.

Initially, B&L was not required to repeat statistics already revealed by the press releases of the HKDH and the SMOH. See Higginbotham, 495 F.3d at 759; In re KeySpan Corp., 383 F.Supp.2d at 377. Moreover, the cause of the keratitis outbreak was still to be determined at the time. In fact, the SMOH stated in a February 20, 2006 press release that "[f]urther investigations [we]re underway to establish the cause of the infection." See Shin Aff. Ex. 21. Further, there is no allegation in the Complaint that any Fusarium keratitis cases had been reported anywhere else in the world as of February 22, 2006 except in Hong Kong and Singapore.

In addition, plaintiffs have not demonstrated falsity with respect to B&L's statements from February 22 through April 12, 2006 that a causal connection had not yet been scientifically established.

Plaintiffs do not assert that B&L had any internal study, finding anything to the contrary when any of these statements were made. Nor have plaintiffs alleged that any health agency purported to find a statistically significant connection prior to the last of the statements by B&L on April 12. Indeed, on April 10, 2006, after Fusarium cases among users of MoistureLoc in the U.S. started to appear, B&L publicly announced it was suspending shipments of the product from the plant that supplied the U.S., Hong Kong and Singapore products. On May 15, 2006, after even more investigation, B&L announced a permanent, worldwide recall of the product.<sup>32</sup>

Moreover, for insider trading activity during the class period to support an inference of bad faith and scienter, it must be "unusual." See Acito, 47 F.3d at 54. To determine whether the trading activity is "unusual" courts consider "the amount of profit from the sales, the portion of the stockholdings sold, the change in volume of insider sales, and the number of insiders selling." See In Re Scholastic Corp. Sec. Litig., 252 F.3d 63, 75 (2d Cir.2001). Here, similar to the accounting matters, plaintiffs' insider-trading theory fails because the timing of the Individual Defendants' stock sales does not add up. Approximately 97% of the stock sales alleged by plaintiffs occurred prior to the earliest date that plaintiffs claim

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<sup>32</sup>Plaintiffs contend that the quality system violations cited in the FDA's October 31, 2006 letter is significant in showing knowledge or recklessness. However, unless B&L had a "time machine," the October 31, 2006 letter cannot raise any inference of scienter for statements or omissions during the Class Period, which ended six months earlier on May 3, 2006. See Gallagher v. Abbott Labs., 269 F.3d 806, 810 (7th Cir. 2001). Further, the conditions at the Greenville plant mentioned in the October 31 letter do not show that the statements regarding MoistureLoc's safety or efficacy were false because none of those conditions had anything to do with Fusarium infections, as both the FDA and CDC made clear.

B&L was on notice of a possible connection between MoistureLoc and Fusarium in Hong Kong (October 20, 2005) and all occurred months or even years before the first reports in Singapore and the U.S. See Shin Aff. Ex. 31; Comp. ¶¶111, 130, 147 and 199. In fact, many of the sales alleged, took place before the product was even on the market, thus defeating any inference of scienter. See Comp. ¶¶115-16, 199. The Court concludes therefore that plaintiffs have failed to adequately plead scienter on behalf of defendants as it relates to MoistureLoc.

**B. Plaintiffs' Failure to Plead that Hahs, Ide, Loughlin, Panzarella, Singh, Stiles or any of the subsidiary defendants made a relevant statement.**

Plaintiffs fail to attribute any statement or omission relating to MoistureLoc to defendants Hahs, Ide, Loughlin, Panzarella, Stiles, BLIO, BL Korea, BL India, BL Japan or BL China. For the same reasons discussed in Point III.B above, the MoistureLoc-related fraud claims are dismissed on the basis of this threshold requirement.

**V. Puffery and Forward-Looking Statements**

Defendants contend that they are not liable for forward-looking statements and puffery. See Defs. Br. at 34-36. Defendants claim that the Complaint refers to numerous statements of "expectations," "outlook," "guidance," "targets," and "projections" as they relate to future earnings and plans, which fall squarely within the PSLRA's definition of forward-looking statements. See id. Moreover, defendants assert that statements, including future performance, which are not worded as a guarantee are per se immaterial and thus not actionable. See id. Plaintiffs argue that while the statements identified by the

defendants were made in documents that include forward-looking statements or puffery, this does not make defendants any less liable for the misleading factual statements, nor does the safe harbor apply to the factual portions of the misstatements. See Pl. Br. at 35. In addition, plaintiffs claim that defendants are liable for materially misleading statements of fact, including financial results, internal controls, and product safety. See id.

In determining whether a defendant has a duty to disclose, the Second Circuit has held that courts must consider the "total mix of information." See San Leandro, 75 F.3d at 811. Courts must also bear in mind that disclosure requirements "are not intended to 'attribute to investors a child-like simplicity.'" See In re Philip Morris Sec. Litig., 872 F.Supp. 97, 101 (S.D.N.Y.1995), *aff'd in part rev'd in part*, 75 F.3d 801 (1996) (citation omitted). Rather, investors are presumed to have the ability to be able to digest varying reports and data. See id.

"[F]orward-looking statements" that "reflect hope, adequately tinged with caution," when considered in the context of the "total mix of information" available to the market, are not misleading. See San Leandro, 75 F.3d at 811. Specifically, the Second Circuit has ruled that general announcements that a company is "optimistic" about its earnings and that it expects a product to perform well, do not require disclosure of possible policies that might contradict those predictions. See id. As the court noted,

Such puffery cannot have misled a reasonable investor to believe that the company had irrevocably committed itself

to one particular strategy, and cannot constitute actionable statements under the securities laws.

See id. Under this standard, a number of statements referred to in the Complaint cannot be considered actionable. For example, statements such as "As you can tell from our share increases [MoistureLoc] is going very well commercially....[W]e've made dramatic improvements in our care kit share.... Almost a 7 or 8 point improvement," is not actionable because it is a general statement of optimism. See Compl. ¶173. This is the type of "subdued general comment[]" about earnings that "lack[s] the sort of definite positive projections that might require later correction." See San Leandro, 75 F.3d at 811 (quoting In re Time Warner Inc. Sec. Litig., 9 F.3d 259, 267 (2d Cir.1993)) (finding comments such as the company "should deliver income growth consistent with its historically superior performance" and "we are optimistic about 1993" to be "relatively subdued comments" that were not actionable)); see also Lasker v. New York State Elec. & Gas Corp., 85 F.3d 55, 58 (2d Cir.1996) (statements about future earnings and the desire to achieve continued prosperity were "just the sort of predictive statements of opinion and belief that courts have found immaterial").

Moreover, the above statement is accompanied by the more cautionary language from the July 27, 2005 press release by Zarrella where he states that "[g]iven our performance to date, and recognizing that new products and further share gains are expected to accelerate top-line growth in the second half of 2005, we have upwardly revised our outlook for the full year." (emphasis added) See id.; Lasker v. New

York State Electric and Gas Corp., 1995 WL 867881, \*6 (E.D.N.Y. 1995); aff'd 85 F.3d 55 (2d Cir. 1996) ("Statements that a company ... has set its most aggressive goals ever are not considered seriously by the marketplace and investors in assessing a potential investment.") (citing Shields, 25 F.3d at 1129; Raab v. Gen. Physics Corp., 4 F.3d 286, 289 (4th Cir. 1993)). Thus, considering the "total mix of information," these "forward looking statements" were "tinged with caution" and thus are not actionable.

Plaintiffs further argue that defendants are liable for materially misleading statements of fact, including financial results, internal controls and product safety and cite to ¶¶ 44-53 and ¶¶ 54-58. As stated in Points III.A.1, A.2, III.B and IV.A above, the Court has found that the allegedly false and misleading statements made by the defendants during the Class Period are not material, in that based on a totality of the information, the risks that the plaintiffs claim were concealed were in fact disclosed, and no reasonable investor would have been misled regarding B&L's accounting matters, internal controls or the safety of MoistureLoc products. Therefore, the statements identified in ¶¶ 44-53, 54-58 and 173-183 of the Complaint are dismissed.

Moreover, the rest of the alleged misstatements, are, "puffery"<sup>33</sup> which is not actionable, or are forward-looking statements that fall

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<sup>33</sup>Several other statements fit the definition of puffery including statement found in paragraphs 83, 91, 99, 107, 114, 116, 117 119 and 136. For example in ¶91 the statement indicates "We are pleased with the solid results we reported today" and have "good reason to be optimistic about our future growth prospects." The Second Circuit has held substantially identical statements immaterial and thus non-actionable. See San Leandro, 75 F.3d at 811.

under the “bespeaks caution” doctrine. For example, the statements alleged in ¶¶87, 91, 95, 103, 107, 114-17 and 119 of the Complaint that refer to expectations, goals, outlook, guidance, targets, and projections in relation to future earnings are not actionable under the Securities law. 15 U.S.C. § 78u-5(i)(1); See In re Eastman Kodak & Co. Sec. Litig., 2006 WL 3149361 at \*5 (W.D.N.Y. 2006) (“forward-looking statements which ‘bespeak caution’ may not form the basis of liability under the federal securities laws”); see also San Leandro, 75 F.3d at 811 (projections of positive earnings, even in light of recent adverse sales figures, not actionable where statements lack definite positive projections) Lasker, 1995 WL 867881 at \*6, (“Statements in the Annual Report regarding future earnings, sales goals, and desire to achieve continued prosperity are just the sort of predictive statements that courts have found immaterial.”) Thus, the earning’s projections and other forward-looking statements challenged in ¶¶87, 91, 95, 103, 107, 114-17 and 119 of the Complaint are dismissed.

#### **VI. Section 20(a) Claims<sup>34</sup>**

To state a claim under Section 20(a), “a plaintiff must show (1) a primary violation by the controlled person, (2) control of the primary violator of the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled

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<sup>34</sup>Section 20(a) may be used to impose joint and several liability upon a person who controls another person who violates Rule 10b-5(b) or certain other provisions of the securities laws. Section 20(a) calls the person who directly violates Rule 10b-5(b) the “controlled person” or “primary violator”; the “primary violator” is said to have committed a “primary violation.” See 15 U.S.C. § 78t(a).



person's fraud." See ATSI, 493 F.3d at 108; In re Alstom SA Sec. Litig., 454 F.Supp.2d 187, 209 (S.D.N.Y.2006) ("In order to establish a prima facie case of liability under § 20(a), a plaintiff must show, *inter alia*, a primary violation by a controlled person.") (quoting Boguslavsky v. Kaplan, 159 F.3d 715, 720 (2d Cir.1998)). Because the Complaint fails to allege a primary violation by a controlled person, Defendants' motion to dismiss the § 20(a) claim is granted.

**CONCLUSION**

For the reasons set forth above, I grant defendants' motion to dismiss plaintiffs' Complaint with prejudice.<sup>35</sup>

**ALL OF THE ABOVE IS SO ORDERED.**

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s/Michael A. Telesca  
MICHAEL A. TELESCA  
United States District Judge

Dated: Rochester, New York  
November 13, 2008

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<sup>35</sup>The Court need not consider and decide defendants' alternative/independent arguments relating to whether the claims against BLIO are time-barred and whether plaintiffs have made a prima facie showing of having personal jurisdiction over defendant Singh since the Court has dismissed the Complaint for failure to state a claim.